GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Ambulatory Surgery Center Letters of Non-Reviewability

Georgia Commission on the Efficacy of the CON Program
October 24, 2005

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History of Review of ASCs

- 1984: First CON ASC Rules Created
- 1987: Revised CON ASC Rules exempted limited purpose ASCs that were physician owned from need and adverse impact analyses
- April 24, 1991: CON statute amended to exempt from CON review certain ASCs that can be established at a cost below a specific amount
- 1991 through 1996: SHPA continued to issue CONs for these exempt ASCs

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Policy Change

- 1996: SHPA discontinued CON review for these excluded ASCs and developed a separate process of review:

Letters of Non-Reviewability

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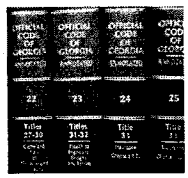
The LNR Concept

- CON Statute, OCGA 31-6, does not mention the term, "Letters of Non-Reviewability" ("LNR")
- But 31-6-47(c) provides that DCH may develop rules to waive the review of exempt projects



- DHR requires some form of written Department authorization prior to issuance of a license

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Statutory Requirements of ASC Exclusion

"New Institutional Health Service" means:

Surgery in an operating room environment, including, but not limited to ambulatory surgery; provided, however, this provision shall not apply to surgery performed in the offices of an individual private physician or single group practice of private physicians if such surgery is performed in a facility that is owned, operated, and utilized by such physicians who also are of a single specialty and the capital expenditure associated with the construction, development, or other establishment of the clinical health service does not exceed the amount of $1 million*

Source: OCGA 31-6-2(14)(G)(iii)

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Regulations

- The Department promulgated rules, which took effect in 1998, to further explain and define the requirements for the statutory ASC exclusion
- 272-2-.07(5)

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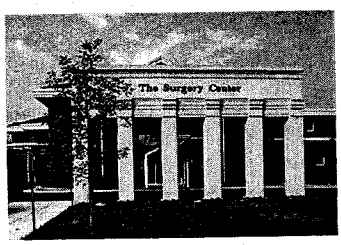
Statutory Requirements of ASC Exclusion

1. Operating room environment
2. Performed in the offices
3. Individual private physician or single group practice of private physicians
4. Owned, operated, and utilized by such physicians
5. Of a single specialty
6. Does not exceed the amount of $1 million*



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Requirement: Operating Room Environment

- OCGA 31-6-2(16.1) and Department's regulations define "operating room environment"
  - Minimum physical plant standards of DHR

Source: Ga. Code of R. & Regs. r. 272-2-.07(4)(g), (h), (j)

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Requirement: Performed in the Office

- Reasonable proximity to a clinical office space
  - Interpreted to mean in the same building as office space

Source: Ga. Code of R. & Regs. r. 272-2-.07(4)(f)

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Requirement: Individual Private Physician or Single Group Practice

- Evidence of Sole Physician Corporation or Group Practice, e.g. articles of incorporation, by-laws, operating agreements
- Affidavit stating that each physician belongs only to one practice

Source: Ga. Code of R. & Regs. r. 272-2-.07(4)(d), (l) - (o)

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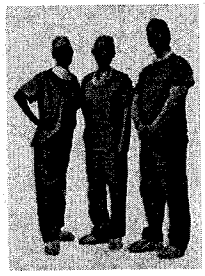
Requirement: Owned, Operated, and Utilized by

- Must have at least 85% licensed physician ownership
- Ownership evidence must be submitted, e.g. stock certificates, operating agreement
- Must submit site entitlement documentation



Source: Ga. Code of R. & Regs. r. 272-2-.07(4)(b)-(e)

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Requirement: Of a Single Specialty

- All members and employed physicians must be of same surgical specialty
- Evidence generally includes an affidavit or documentation of specialty listed with Composite Medical Board

Source: Ga. Code of R. & Regs. r. 272-2-.07(4)(b)

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Requirement: Of a Single Specialty (cont'd)

- Neither Statute nor Regulations define "single specialty"
- Regulations define "multi-specialty"
  - Any ASC offering general surgery or any combination of general surgery and any number of the following specialties:
    - Dentistry/oral surgery
    - Gastroenterology
    - OB/GYN
    - Ophthalmology
    - Podiatry
    - Pulmonary Medicine
    - Orthopedics
    - Otolaryngology
    - Pain Management/ Anesthesiology
    - Plastic Surgery
    - Urology

Source: Ga. Code of R. & Regs. r. 111-2-2-.40(2)(j)

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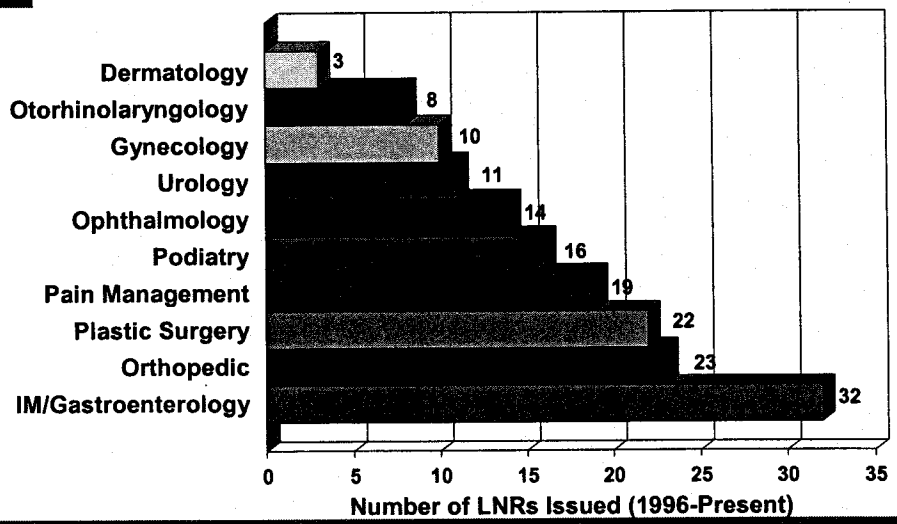
Historical Data: Specialty



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Requirement: Does not Exceed the Amount of $1 Million*

- Amount is adjusted annually for inflation in construction indices
  - Currently $1.515 M
- Includes all capital expenditures made by or on behalf of the physician or group in establishing and developing the ASC for the first three years including:
  - Construction
  - Equipment
  - Legal, consulting, and administrative fees
  - Interest during construction
  - Furnishings

Source: Ga. Code of R. & Regs. r. 272-2-.07(4)(i), (k), (p), (q)

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Requirement: Does not Exceed the Amount of $1 Million* (cont'd)

- In calculating the threshold all "associated and simultaneous" expenditures and activities must be included, for example:
  - simultaneous construction of clinical offices
- Estimates are provided during the review of the LNR request; final cost reports must be submitted to validate that the threshold has not been exceeded

Source: OCGA 31-6-2(14) & Ga. Comp. R. & Regs. r. 111-2-2-.01(8)

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LNR Challenges

- During the review process, an LNR request may be challenged by any interested party
  - The Department issues weekly notice of all new LNR requests
  - Challengers submit written allegations and reasons for Departmental denial
  - Requesters have opportunity to respond to all allegations

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Options if LNR Request Denied

- Appeal
  - Only the requesting party may appeal a denial
  - Challengers may not appeal if approved
  - Challengers may intervene in an appeal of a denial

OR

- Apply for a CON

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Differences between CON and LNR Processes

LNR

- No Need Analysis
- No Commitment to Indigent and Charity Care
- Only Requesting Party may Appeal
- Limited to Statutory Restrictions
- No Review of Quality
- No Review of Fees
- No Requirement to Report Statistical Data

CON

- Calculated Need Must Exist
- Must Commit to Provide 3% of annual AGR to Indigent and Charity Care
- Any Competing Entity may Appeal
- No limitations on ownership, location, cost, specialty, etc.
- Minimum quality standards must be met
- Fees must be Reasonable
- Must Report Annual Data

Letters of Non-Reviewability

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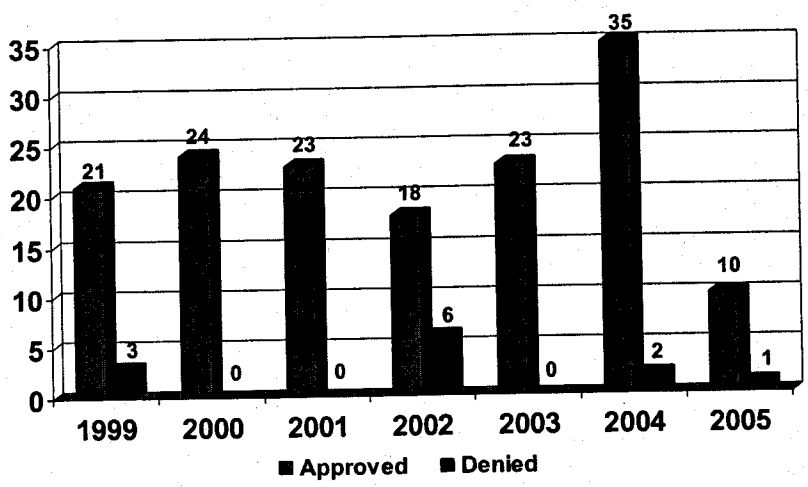
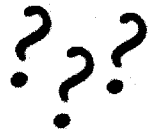
Historical Data: Requests Received



Letters of Non-Reviewability

Questions



Questions

State Health Planning Agency

Policy Announcement 001-96

Planning
Policy Implementation
Data Collection and Analysis
Commitment to Quality Service

Discontinuation of Voluntary Certificate of Need Review for Physician-owned, Limited-purpose Ambulatory Surgery Centers

Effective April 1, 1996, the State Health Planning Agency (SHPA) will no longer accept Certificate of Need (CON) applications from private physicians who propose to have surgery centers located within their offices classified as Ambulatory Surgery Centers (ASCs) **if such surgery centers are not otherwise subject to mandatory CON review.** This change will not affect physician-owned, limited-purpose ambulatory surgery centers that were previously granted CONs and licenses.

Background

Private physicians who have surgical capacity as part of their offices are unable to obtain a "facility fee reimbursement" from various payers, including Medicare, for surgical services performed within their offices unless their office-based surgery centers are licensed and certified by the Department of Human Resources' Office of Regulatory Services (ORS) as an ambulatory surgery center in accordance with State licensure law. In the past, ORS required private physicians to obtain CON approval as an ambulatory surgery center from SHPA before a surgery center located within their offices could be licensed as an ASC. In response to the previous position of ORS and in an effort to support physicians, SHPA amended its ambulatory surgery center rules in September of 1987 to create a subcategory of ASCs known as Physician-owned, Limited-purpose Ambulatory Surgery Centers. This rule allowed physicians who had surgery centers located within their private offices voluntarily to request CON review under certain conditions. The conditions contained within the rule were oriented primarily around the provision of high-quality surgical services and did not involve SHPA's numerical need methodology, which is used for other subcategories of ASCs.

Reason for Discontinuation of Review

With certain exceptions, the current CON statute, upon which SHPA's rules are authorized and based, expressly provides that the CON law shall **not** apply to the offices of private physicians or dentists, whether for individual or group practice. There are, however, two statutory circumstances regarding surgical services in which a CON is specifically required in relation to the offices of private physicians and dentists.

Multispecialty Facilities

The law requires prior CON review and approval when an individual private physician or single group practice of private physicians proposes to perform **more than one surgical specialty** within the office-based surgical center. This requirement for multispecialty ASCs applies regardless of the cost involved in the construction, development, or other establishment of the surgical center.

Single-specialty Facilities in Excess of the Applicable Capital Expenditure Threshold

The second circumstance is related to an individual private physician or a single group practice of private physicians proposing to perform a **single** surgical specialty within the office-based

surgical center. The law expressly requires prior CON approval if the physician(s) expects to exceed a capital expenditure of $1,124,250 during the construction, development, or other establishment of the surgical center. **The dollar amount changes annually.**

Thus, even though it is a voluntary process, the Physician-owned, Limited-purpose Ambulatory Surgery Center rule is inconsistent with the CON statute.

Future Treatment of Physician Office-based Ambulatory Surgery Centers

Individual private physicians or single group practices of private physicians will continue to obtain CON review and approval prior to developing office-based surgical centers which meet either of the two circumstances addressed above. Individual private physicians or single-specialty group practices of private physicians who want to have their otherwise nonreviewable surgical centers licensed as ASCs by ORS will no longer be eligible for a CON even on a voluntary basis. Instead, the physician(s) will need to obtain a letter of nonreviewability from SHPA before applying to ORS for a State license. This will require sending SHPA a written request that describes the scope of the proposal and specifically indicates why the proposal is not considered to be reviewable, e.g. the physician ownership, office location, single surgical specialty, and/or the anticipated capital expenditure. SHPA will then issue a written response which either confirms the nonreviewability of the proposal or which indicates that a CON application should be filed. If applicable, the letter of nonreviewability should be attached to the licensure application and will be accepted by ORS as evidence of SHPA review.

The letter of nonreviewability does not grant unlimited authorization as an ASC. The license issued by ORS will be restricted to the terms and scope of the nonreviewability letter issued by SHPA. If at any time the circumstances of the facility change in such a way that it meets the CON requirements of prior mandatory review, the owner(s) must immediately apply for the appropriate CON or face a penalty of up to $5,000 a day for violating CON law.

For further information, contact:

Mr. John Hamilton
Legal Services Officer
(404) 679-4865

Mail requests for letters of nonreviewability to:

Ms. Pamela Stephenson, Director
Division of Regulatory Review
(404) 679-4879

State Health Planning Agency
4 Executive Park Drive, N.E.
Suite 2100
Atlanta, Georgia 30329

Mandamus Actions

What is a Mandamus Action?

In a mandamus action, a party is asking a court to "mandate" a governmental official to perform some ministerial act the requesting party claims the law requires the official to perform.

How Many Mandamus Actions Have Been Filed Over the Last Two (2) Years?

Over the course of the last two (2) years, approximately ten (10) mandamus actions have been filed regarding Letters of Non-Reviewability that have been issued by the Department of Community Health.

How Much Time is Required to Respond to a Mandamus Action?

Approximately 100 hours, on average, were required for the Attorney General's Office to address each mandamus action. DCH is unable to estimate how many hours applicants and their counsel have utilized to defend their interests in these actions.

List of Mandamus Actions:

A. Open Case

1. Georgia Alliance of Community Hospitals v. Tim Burgess (Imaging Associates of Canton, LLC), Fulton Superior Court No. 2004cv90244 (J. Johnson) (filed August 25, 2004)

LNR Issue Date:	**January 23, 2004**
Business Entity:	**Imaging Associates of Canton, LLC**
Location:	**Canton, Georgia**
Proposed Capital Expenditure:	**$711,021.71**
Actual Capital Expenditure:	**NA**

The Georgia Alliance of Community Hospitals ("Alliance") filed a complaint and application for Writ of Mandamus seeking a determination and judgment that the applicant had developed the project in violation of CON requirements.

The applicant intervened by Consent Order dated April 27, 2005. The Alliance asserts the following:

a. the capital expenditure for the ASC exceeded the established threshold because certain construction costs specific to other equipment were excluded

The parties filed Motions for Summary Judgment on September 20, 2005 and responses are due October 31, 2005. The hearing is set for November 14, 2005.

B. Closed Cases

1. Georgia Alliance of Community Hospitals v. Tim Burgess (North Atlanta Scan Associates, Inc.)(Superior Court No. 2004cv89690)(Tusan)(Filed May 29, 2003)

LNR Issue Date:	**March 9, 2001**
Applicant:	**North Atlanta Scan Associates, Inc.**
Location:	**Atlanta, Georgia**
Proposed Capital Expenditure:	**$424,720**
Actual Capital Expenditure:	**N/A**

This case involved the filing of two complaints and applications for Writs of Mandamus by the Georgia Alliance of Community Hospitals ("Alliance") and Diagnostic Imaging of Atlanta. The two cases were consolidated before Fulton Superior Judge Tusan. The Alliance and Diagnostic Imaging of Atlanta made the following assertions in their complaints:

a. the relocation of a diagnostic treatment rehabilitative center requires CON review
b. the applicant failed to include the expenditure of new diagnostic and therapeutic equipment which exceeded the applicable equipment expenditure

Subsequent to the filings of the complaints, DCH rescinded the LNR and issued a Cease and Desist Order against NASA. The Alliance then dismissed its mandamus action.

2. Georgia Alliance of Community Hospitals v. Timothy Burgess (Renaissance Surgical Centre, LLC) Fulton Superior Court No.2004cv78301 (J. Brogdon) (filed November 2003).

LNR Issue Date:	**August 7, 2003**
Practice:	**Renaissance Plastic Surgery, P.C.**
ASC:	**Renaissance Surgical Centre, LLC**
Specialty:	**Plastic surgery**
Location:	**Macon, Georgia**
Proposed Capital Expenditure:	**$1,083,046**
Actual Capital Expenditure:	**$951,720**

The Alliance filed a complaint and application for Writ of Mandamus seeking a determination and judgment that the applicant had developed the project in violation of CON requirements. The Alliance asserted the following:

a. the request failed to provide all costs associated with the design and construction of the ASC
b. the ASC is owned by separate entity, and therefore is not in the "offices" of the physicians
c. the applicant provided insufficient documentation regarding square footage associated with business offices and common areas
d. the request failed to provide sufficient information regarding costs associated with consultants

On November 18, 2004 a settlement agreement was executed regarding the case and a dismissal was granted on November 16, 2004.

3. Georgia Alliance of Community Hospitals v. Timothy Burgess(Lanier Eye Associates, LLC d/b/a Advanced Eye Surgery and Laser Center)(Fulton Superior Court No. 2004cv95309) (J. Lane)(Filed December 28, 2004)

LNR Issue Date:	**January 30, 2002**
Practice:	**Lanier Eye Associates, LLC**
ASC:	**Advanced Eye Surgery and Laser Center**
Specialty:	**Ophthalmology**
Location:	**Gainesville, Georgia**
Proposed Capital Expenditure:	**$1,136,531**
Actual Capital Expenditure:	**Unknown**

The Alliance filed a complaint and application for Writ of Mandamus seeking a determination and judgment that the applicant had developed an ASC in violation of CON requirements. The Alliance asserted the following:

a. the ASC licensed by DHR under O.C.G.A. § 31-7-1 cannot be a "physician owned" office-based clinic eligible for the exemption of OCGA § 31-6-2(14)(G)(iii)
b. applicant failed to document all expenditures for construction, equipment and furnishings for the project

The parties executed a settlement agreement and the Alliance dismissed its case in June 2005.

4. West Paces Diagnostic Imaging v. Timothy Burgess(The Palisades at West Paces Imaging Center, LLC)(Fulton Superior Court No.2004cv84820)(J. Dempsey)(filed April 19, 2004)

LNR Issue Date:	**February 17, 2004**
Applicant:	**The Palisades at West Paces Imaging Center, LLC**
Location:	**Atlanta, Georgia**
Proposed Capital Expenditure:	**$707,148**
Actual Capital Expenditure:	**N/A**

The Alliance filed a complaint and application for Writ of Mandamus seeking a determination and judgment that the applicant had developed the project in violation of CON requirements. The Alliance asserted the following:

a. the applicant failed to include costs associated with the purchase of additional MRI equipment
b. the applicant did not include, or improperly valued, certain categories in its line item valuation sheet such as transportation, insurance and rigging and no-equipment capital expenditures

The Alliance dismissed its case when DCH revoked the Letter of Non-Reviewability on August 15, 2005 upon making a determination that additional costs were attributable to the project which would result in the project exceeding the capital expenditure threshold.

5. Georgia Alliance of Community Hospitals v. Timothy Burgess(Albany Diagnostic Center, LLC)(Superior Court No. 2004cv88735 (J. Goger)(Filed July 23, 2004)

LNR Issue Date:	**May 18, 2004**
Applicant:	**Albany Diagnostic Center, LLC**
Location:	**Albany, Georgia**
Proposed Capital Expenditure:	**$725,790**
Actual Capital Expenditure:	**N/A**

The Alliance filed a complaint and application for Writ of Mandamus seeking a determination and judgment that the applicant had developed the project in violation of CON requirements. The Alliance asserted the following:

a. applicant intended to install and operate a MRI unit that was initially installed and operated by Royston Diagnostic Clinic in Royston, GA who had previously received a Cease and Desist Order from the Department regarding the same piece of equipment
b. applicant failed to include all expenditures associated with the installation of the MRI

On April 21, 2005, the Superior Court heard the parties' Motions for Summary Judgment and granted DCH's motion as well as Albany Diagnostic Center. On September 19, 2005, the Supreme Court of Georgia dismissed the Alliance's appeal of the Superior Court's decision in favor of DCH.

6. Georgia Alliance of Community Hospitals v. Tim Burgess(Hand& Upper Extremity Center of Georgia, P.C., Hand & Upper Extremity Surgery Center of Georgia LLC), Fulton Superior Court No. 2004cv84330 (J. Baxter)(April 8, 2004)

LNR Issue Date:	**March 5, 2004**
Practice:	**Hand & Upper Extremity Center of Georgia, PC**
ASC:	**Hand & Upper Extremity Surgery Center of Georgia, LLC**
Specialty:	**Orthopedic**
Location:	**Atlanta, Georgia**
Proposed Capital Expenditure:	**$1,149,688**
Actual Expenditure:	**$1,119,471**

The Alliance filed a complaint and application for Writ of Mandamus, seeking a determination and judgment that the applicant had developed the ASC in violation of CON requirements. The Alliance made the following assertions in its complaint:

a. the ASC was not in the principal "office" of the owning physicians or group practice and that the ASC was owned by separate entity set up by the physicians
b. the ASC was not within reasonable proximity of the clinical offices of the group practice;
c. the capital expenditure for the ASC exceeded the established threshold
d. the applicant failed to show site entitlement

DCH and the two other defendants filed Motions for Summary Judgment in September 2004 and June 2004, respectively. During the hearing on October 7, 2005, the Judge announced from the bench his decision to dismiss the Alliance's case.

7. Georgia Alliance of Community Hospitals v. Tim Burgess (Ear, Nose and Throat of Atlanta, LLC), Fulton Superior Court No. 2004cv87081 (J. Moore) (filed June 14, 2004)

LNR Issue Date:	**April 8, 2004**
Practice:	**Ear Nose & Throat of Atlanta, LLC**
ASC:	**ENT Surgery Center of Atlanta, LLC**
Specialty:	**Otorhinolaryngology**
Location:	**Atlanta, Georgia**
Proposed Capital Expenditure:	**$1,048,296**
Actual Capital Expenditure:	**N/A as of April 2005**

The Alliance filed a complaint and application for Writ of Mandamus seeking a determination and judgment that the applicants had developed an ASC in violation of CON requirements. The Alliance asserted the following:

a. the ASC is owned by a separate entity, and therefore is not in the "offices" of the physicians
b. the ASC is not owned by a physician or group practice
c. the ASC is not within reasonable proximity of the group practice
d. the capital expenditure for the ASC exceeded the established threshold
e. the applicant provided insufficient documentation regarding site entitlement, plans, loans and guarantees

ENT Surgery Center of Atlanta, LLC (ENT) intervened. ENT filed a Motion for Summary Judgment on November 29, 2004 and DCH filed a Motion for Summary Judgment on January 14, 2005. The Alliance filed a response Cross-motion for Summary Judgment on February 1, 2005. The Superior Court entered judgment against the Alliance on August 8, 2005. The Alliance's Application for Discretionary Appeal was filed with the Georgia Supreme Court on September 12, 2005 and the opposing brief was filed on September 22, 2005.

On October 12, 2005, the Georgia Supreme Court denied the Alliance's Application for Discretionary Appeal from the Superior Court's decision, which therefore affirmed the Superior Court's decision.

8. Georgia Alliance of Community Hospitals v. Tim Burgess(Gastroenterology Associates of Central Georgia, LLC), Fulton Superior Court No. 2004cv84749 (J. Campbell) (filed April 19, 2004)

LNR Issue Date:	**March 8, 2004**
Practice:	**Gastroenterology Associates of Central Georgia, LLC**
ASC:	**Endoscopy Center of Middle Georgia, LLC**
Specialty:	**Gastroenterology**
Location:	**Macon, Georgia**
Proposed Capital Expenditure:	**$1,342,506**
Actual Expenditure:	**$1,130,876**

The Alliance filed a complaint and application for Writ of Mandamus seeking a determination and judgment that the applicants had developed an ASC in violation of CON requirements. The Alliance made the following assertions in its complaints:

a. the ASC was not in the "offices" of the physician owners because it was located on a separate floor;
b. the ASC is operated by a separate entity and not by physicians or group practice
c. the ASC not in reasonable proximity to the physicians' offices
d. the capital expenditure for the ASC exceeded the established threshold

e. the applicant provided insufficient documentation

The Alliance filed a Motion for Summary Judgment on May 23, 2005 and DCH filed a Response and Cross-motion for Summary Judgment on June 22, 2005. After the ruling by the Supreme Court of Georgia in case 7 above, the Alliance voluntarily dismissed this case on October 18, 2005.

9. Georgia Alliance of Community Hospitals v. Tim Burgess (Specialty Clinics of Georgia Orthopaedics, PC), Fulton Superior Court No. 2004cv95307 (J. Glanville) (filed December 28, 2004)

LNR Issue Date:	**September 16, 2004**
Practice:	**Specialty Clinics of Georgia Orthopaedics, P.C.**
ASC:	**Specialty Orthopaedics Surgery Center, LLC**
Specialty:	**Orthopedics**
Location:	**Gainesville, Georgia**
Proposed Capital Expenditure:	**$1,248,127**
Actual Capital Expenditure:	**$40,413 as of April 2005**

The Alliance filed a complaint and application for Writ of Mandamus seeking a determination and judgment that the applicant had developed the project in violation of CON requirements. The Alliance asserted the following:

a. the total cost of the ASC exceeds the capital expenditure threshold
b. the LNR request omitted and understated substantial items of cost
c. the LNR request failed to contain information required by DCH regulation
d. the ASC licensed by DHR under O.C.G.A. § 31-7-1 cannot be a "physician owned" office-based clinic eligible for the exemption of OCGA § 31-6-2(14)(G)(iii)
e. the ASC is not owned and operated by a "single specialty" because a multi-specialty group actually proposed, developed and constructed the ASC
f. the ASC is not owned and operated by physicians because it is operated under a separate corporate entity

The applicant intervened by Consent Order presented February 10, 2005. A Motion to Compel was filed by the Alliance. In response, the applicant filed a Motion for Protective Order in September 2005. After the ruling by the Supreme Court of Georgia in case 7 above, the Alliance voluntarily dismissed this case on October 18, 2005.

GEORGIA STATE HEALTH PLAN
COMPONENT PLAN

DRAFT

AMBULATORY SURGICAL SERVICES

HEALTH STRATEGIES COUNCIL
GEORGIA DEPARTMENT OF COMMUNITY HEALTH
DIVISION OF HEALTH PLANNING
2 Peachtree Street, NW
Suite 34.262
Atlanta, GA 30303

For review and input by Health Strategies Council at their November 21, 2003 meeting

DRAFT
Revised November 18, 2003

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PREFACE

This Component Plan is a product of the Health Strategies Council and the Georgia Department of Community Health/Department of Health Planning, pursuant to the provisions of O.C.G.A. 31-5A-1 et seq., and 31-6-1, et seq., and Ga. Comp. R. and Regs. 272-2-1 et. Seq. The purpose of the Plan is to identify and address issues that affect the operation of general hospitals and to recommend goals, objectives and system changes to achieve official state health policies.

This Plan has been produced through an open, public participatory process developed and monitored by the Health Strategies Council appointed by the Governor. The Plan is effective upon approval by the Council and the Board of Community Health and supersedes all related sections of previous editions of the State Health Plan and any existing related Component Plan.

For purposes of the administration and implementation of the Georgia Certificate of Need (CON) program, criteria and standards for review (as stated in the Ga. Comp. R. & Regs., Chapters 272-1, 272-2 and 272-3) are derived from this Component Plan. The Rules, which are published separately from the Plan and which undergo a separate public review process, are an official interpretation of any official Component Plan which the Regulatory Review Section of the Office of General Counsel has the legal authority to implement. The Rules are reviewed by the Health Strategies Council, prior to their adoption by the Board of Community Health, for their consistency with the Plan. The Rules, as a legal document, represent the final authority for all Certificate of Need review decisions.

Any questions or comments on this Component Plan should be directed to:

Georgia Department of Community Health
Division of Health Planning
2 Peachtree Street, N.W., Suite 34.262
Atlanta, Georgia 30303

◆

Telephone: (404) 656-0655

I. INTRODUCTION

A. STATEMENT OF PUBLIC POLICY FROM THE DEPARTMENT OF COMMUNITY HEALTH

The Department of Community Health (DCH) was created in 1999 by the Georgia General Assembly in response to a growing concern about fragmentation of health care delivery at the state level. The legislation outlined several purposes for the Department including the development of a state health care infrastructure that would be more responsive to the consumers it serves while improving access to services and healthcare coverage and promoting wellness. The Department has embarked on this charge with great enthusiasm and fervor. Since the formation of the Department of Community Health, several components of the State Health Plan have been revised to reflect the new regulatory focus and policy integration.

The Department is responsible for managing the state's health planning program which establishes standards and criteria for awarding Certificates-of-Need to health care facilities and certain specialized diagnostic or treatment services. The Department works to contain health care costs by avoiding unnecessary duplication of services, equipment and facilities and helps to enforce quality-of-care standards. The Department is committed to ensuring that providers assume a share of the responsibility for the health care needs of low-income citizens and underserved or at-risk members of their local community. Financial access, clinical proficiency and community outreach are cornerstones of the Department's mission.

The Department of Community Health has chosen to update the Ambulatory Surgical Services Plan and Rules to describe the current regulatory framework within which providers will be required to operate and to ensure the protection of the public and payor systems. The previous state health component plan and rules governing the need for and operation of ambulatory surgery services were adopted in 1998. These rules address multi-specialty and limited-purpose freestanding ambulatory surgery services. The majority of physician-owned, single-purpose surgical centers are exempted from Certificate of Need rules by law. Since the inception of the current component plan, concern has been raised by certain providers and advocates about elements of the need methodology, the planning areas, adverse impact on other providers, and the overall scope of the plan. DCH Board Members and a wide range of stakeholders have suggested that the plan needs to be reviewed and updated.

It is the Department's hope that this revised plan and accompanying rules will incorporate a range of strategies to clarify and strengthen the planning and regulatory review process. The Department is committed to :

- Maintaining an objective need methodology for ambulatory surgical services;
- Promoting access to ambulatory surgical services by fostering an environment that encourages the delivery of services to all Georgia citizens;
- Incorporating clinical and other advances occurring in ambulatory surgical services in its planning and regulatory rules;
- Ensuring uniformity between state agencies by adopting common service delivery regions by moving away from health planning areas and utilizing State Service Delivery Regions and

- Advocating the Department's commitment to continuity of care, quality improvement standards and data reporting systems for health services, including freestanding ambulatory surgery services in the state.

B. PLANNING PROCESS

The first ambulatory surgery services component of Georgia's State Health Plan was completed in 1984. This plan dealt specifically with ambulatory surgery centers that were owned and/or operated by hospitals or other entities and did not include private physician or dental offices. The plan was revised in August 1987 to allow physicians, who had been providing outpatient surgery services within their own offices, to be classified as physician-owned, limited-purpose ambulatory surgery centers so that they could receive Medicare facility fee reimbursement for services rendered in this setting. The plan was revised again in July 1989 to include the most recent Georgia-specific ambulatory surgery use rate when computing need instead of the non-specific 30% rate designated in the 1984 plan.

The rapid growth of ambulatory surgery programs in the state and the passage of HB 508, in March 1991, which regulates diagnostic, treatment, and rehabilitation centers that offer ambulatory surgery services outside of a hospital setting, provided the impetus once again to update the plan. In August 1995, Georgia's Health Strategies Council (Council), a 27-member board appointed by the Governor, responsible for developing Georgia's State Health Plan and addressing policy issues concerning access to health care services, voted to convene a Modified Technical Advisory Committee (TAC). Members consisted of the Council's Ambulatory/Primary Care Standing Committee. The Modified TAC held its first meeting in November 1995, and formed a Capacity/Utilization/Adverse Impact Subcommittee, which met in November and December 1995, and a Survey Work Group, which met in December 1995. These subcommittees focused on such issues as the availability of ambulatory surgical services in Georgia, local and national trends, and definitions of critical terms including capacity and utilization. After consideration of several options, the TAC recommended the development of a plan and rules that did not include a specific numerical need formula or a definition of 'capacity', but one that would continue to address the public policy objectives of access and quality. This strategy was based on the following considerations:

- Ambulatory surgery services provide low-cost alternatives to inpatient surgery services in Georgia;
- Ambulatory surgery services should remain under CON regulation, but 'capacity and volume' criteria of the need methodology should be eliminated. TAC members agreed that market forces, particularly those in urban areas, would serve to control excess investment;
- The public policy objectives of access and quality should continue to be addressed in the plan and rules.
- Ambulatory surgery rules should be compatible with the current healthcare market place so that economic realities (i.e. competition, managed care, and numbers of providers) can co-exist with regulation.

In February 1996, the TAC presented the draft plan and rules to the Council. The Council voted to issue the draft Plan and rules for public comment. The proposed plan and rules were issued for public comment in March 1996. A second public comment period was held in June 1996. During both comment periods, the public expressed concern about the absence of a numerical need methodology. They were concerned about whether the proposed rules would provide adequate justification for the Agency (now the Division of

Health Planning) to legally defend its regulatory review decisions. There was also some concern about the assumptions of the strength of market forces on ambulatory surgery services in Georgia. Considering the strength of the public comments, in August 1996 the Council voted not to adopt the proposed rules. Following additional staff research and input from the Council a draft plan and CON rules, which incorporated an objective need methodology, were issued for public comment in April 1998. In June 1998, the plan and rules were formally adopted.

Since the inception of the 1998 component plan, concern continued to be raised about elements of the need methodology, the planning areas, adverse impact on other providers, and the scope of the plan. DCH Board members charged the Department of Health Planning and the Council to review and update the Ambulatory Surgery Services Plan and Rules.

The revision and adoption of a component plan is a deliberate process by the Council and involves the establishment of a TAC. At their May 2002 meeting, Council members established three new standing committees, namely Acute Care, Long Term Care and Special & Other Services. Ambulatory Surgery Services fell under the purview of the latter committee. This committee was chaired by David M. Williams, M.D. and charged with periodically addressing changes occurring in the healthcare industry that would impact the way that specialized services are delivered. At its January 2003 meeting, the Special & Other Services Standing Committee recommended the establishment of a TAC for freestanding ambulatory surgical services. At its February 2003 meeting, the Council voted to convene an Ambulatory Surgical Services TAC.

Members of the Ambulatory Surgical Services TAC (See Appendix A) represented varied geographic regions of the state and are members of a wide variety of constituent groups, including state agencies, consumers, professional associations, advocates, provider groups, and payors. William G. Baker, Jr. MD, President, Atlanta Regional Health Forum, Inc and member of the Council, chaired this 18-member group. The TAC was asked to develop a new component plan and related rules to govern the establishment, replacement or expansion of ambulatory surgery services. The Council charged the TAC with producing two work products:

- A proposed new component plan for consideration by the Council that would address the development, delivery and maintenance of statewide ambulatory surgical services and
- A set of proposed rules for consideration by the Council and the Board of Community Health.

The TAC met five times between May 2003 and November 2003. They examined a plethora of statewide data and planning materials and closely examined other state methodologies and planning processes, materials from national accrediting bodies, professional associations and considerable public input. During their deliberation process, they agreed that the following concepts should be represented in the core criteria of the ambulatory surgery rules in the State of Georgia:

- Numerical Need methodology
- Exception to Need Language (cost, quality, financial and geographic access)
- Definition of "single specialty" and development of a list of core specialties
- Financial Accessibility, including Indigent and Charity Care Commitments
- Definition of operating rooms and determination as to which rooms should be counted in the need methodology (look at Medicare rules and regulations)
- Determination of whether to use "patients" or "procedures" in need determinations (look to

Medicare definition)
- Continuity of Care Standards
- Quality of Care Standards
- Determination of planning area boundaries (health planning areas versus state service delivery regions)
- Community focus (availability of services locally)
- Clarification of Relocation/Replacement Issues

This list of planning concepts was augmented and refined during the TAC's deliberations and provided the backbone for the development of the Ambulatory Surgical Services Plan and Rules. Following three committee meetings, development of draft rules and significant committee input, the TAC appointed a subcommittee to convene a Public Forum. This subcommittee's responsibility was to preside at a forum to allow the public additional opportunities for input into the plan development and rules process. The Public Forum was held in Bibb County, a centrally located county in the state. Nearly 30 persons attended; nine (9) of whom presented oral comments. Others provided feedback through written submissions. Two additional TAC meetings were held to formally adopt all of the planning principles in the plan and rules.

The current rule incorporates certain aspects of the earlier version of the rules, but also includes a range of other considerations. Some of the key differences between these rules and the earlier version include the following:

- Expanded and updated definitions;
- Change of terminology from "limited purpose" to "single specialty" and a clear delineation of single specialties;
- Allowance for replacement facilities in narrow situations (exempt from the numerical need methodology and adverse impact standard).
- Incorporation of some straightforward options for exceptions to the numerical need methodology;
- More detailed adverse impact criteria and inclusion of some protections for safety net hospitals; and
- Enhancement of quality, continuity and financial accessibility standards;

Information used in the development of this plan and accompanying rules is the result of review of ambulatory surgical services plans from other states, research of current literature, review of the rules of the American Society of Anesthesiologists, American Association for Accreditation of Ambulatory Surgery Facilities, Accreditation Association for Ambulatory Health Care and other appropriate agencies, considerable public input and deliberation by the TAC. The Department's legal team also provided guidance to the Department and the TAC in the final development of the rules.

This planning document represents a consensus from the Ambulatory Surgical Services Technical Advisory Committee and was presented for consideration at the Council's meeting in November 2003. Upon the Council's approval of the recommendations and concepts that are outlined in the Ambulatory Surgical Services component of the state health plan, the rules were forwarded to the Board of Community Health for posting for public comment. The TAC feels confident that this document provides an excellent structure and process to assure that high quality ambulatory surgery services are provided in an efficient and cost effective manner to the citizens of the State of Georgia.

II. OVERVIEW

A. OVERVIEW OF NATIONAL TRENDS

Ambulatory surgical services have historically provided safe and cost effective outpatient care for patients that may have otherwise been admitted to a hospital. A report published by the Medicare Payment Advisory Committee (MedPAC) identified the following factors that impact the growth of Ambulatory Surgery Centers (ASCs): the shift of services from inpatient settings to ambulatory care settings; growth in ASCs share of ambulatory services; changes in practice patterns and medical technology; benefits to patients; and benefits to physicians.

The increase in the number of surgeries performed in freestanding ambulatory surgical facilities has outpaced the growth of hospital outpatient departments and physician offices. Payor incentives, patient convenience, and physician preference can be attributed to the growth in the volume of surgeries and procedures performed in freestanding outpatient settings. Payors may cover more of the cost for patients that receive services in an ambulatory surgery center. Some data suggest that patients may prefer the more convenient locations, lower insurance co-payments, decreased exposure to infectious agents, and timely appointment scheduling that are provided by ambulatory surgery centers.

Physicians are able to perform more surgeries in an ambulatory surgery setting because of the specialized services these centers provide. In addition, physicians are able to easily reserve appointment times in an ambulatory surgery center because there is a lack of unpredictable demands that may be encountered in a hospital outpatient department. Also, investing in ambulatory surgery centers allows physicians to increase their revenues.

Hospitals

Some hospital leaders have expressed concern about the proliferation of for-profit specialty services and contend that freestanding ambulatory surgery facilities and other specialty centers siphon off higher paying and insured patients as well as carve out the most profitable health services away from the hospital setting. Hospital proponents argue that this trend is detrimental to community hospitals particularly because specialty services compete with the more profitable services offered in hospital settings.

A report by the American Hospital Association acknowledges that, over the past twenty years advances in medical technology and practice patterns have dramatically changed the way healthcare is delivered in surgical settings. A growing number of medical procedures that were once delivered in a hospital-based inpatient setting are now safely performed in freestanding ambulatory surgery facilities. Advances in technology have made traditional surgeries less invasive and reduced the necessary post-surgery recovery time. These advances have allowed patients to avoid hospital overnight stays and made outpatient surgeries more convenient to physicians and patients.

Between 1980 and 2000, given the changing shifts in practice patterns primarily driven by insurance reimbursement methodologies and dramatic advances in medical technology, hospitals responded to the shift in surgical services from inpatient services to outpatient settings and began to downsize inpatient beds and shift resources to outpatient settings. The shift from inpatient to outpatient settings has continued to

grow with technological advances and has resulted in the lowering of healthcare costs to employers and payors.

Surgical Specialties

The Federated Ambulatory Surgery Association (FASA), a nonprofit association representing the interests of ambulatory surgery centers, reported that the majority of procedures performed in ASCs were either ophthalmology or gastroenterology procedures. Among the procedures that are performed on an outpatient basis, include but are not limited to the following: ophthalmology, plastic and reconstructive surgery, podiatry, orthopedics, pain management, gynecology, and dermatology. Some of these specialties are operated in a single-specialty environment, where a provider offers services in one specialty area while other providers offer services in multi-specialty areas.

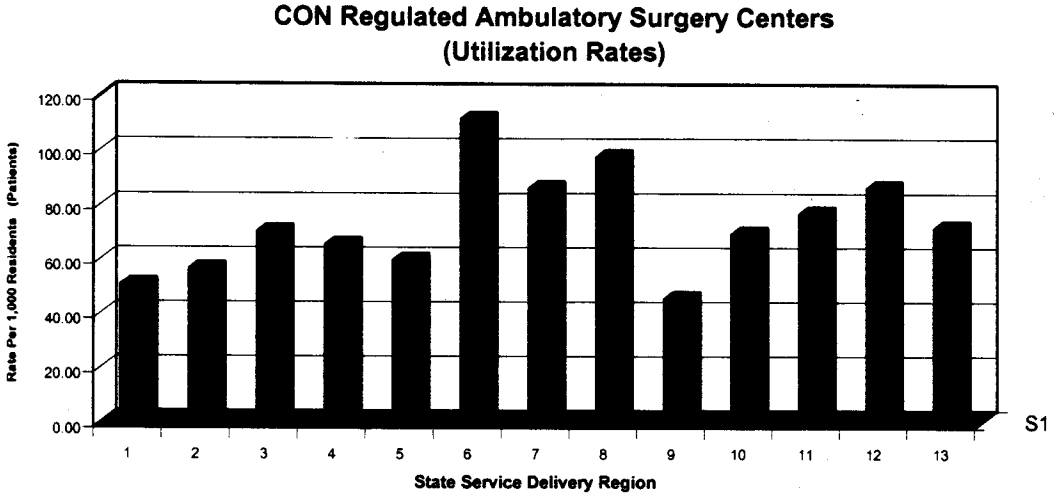
Single-Specialty, Physician-Owned Surgery Centers

Emerging technological trends have led to the safe performance of complicated surgical procedures in office-based settings. In Georgia, single-specialty, physician-owned facilities, the cost of which falls below the designated CON threshold, are statutorily exempt from obtaining a Certificate of Need. A majority of the safety concerns that arise from physician offices appear to deal with factors contributed to inadequate anesthesia monitoring and the performance of too many procedures on one patient at one time. Those single-specialty, physician-owned facilities that trigger the Certificate of Need threshold must submit a CON application.

B. AMBULATORY SURGICAL SERVICES IN GEORGIA

Georgia has become one of the ten most populous states in the nation with an estimated population of 8.1 million in 2000. The US Census estimated that Georgia's population grew 26.4% in a ten-year period, from 1990-2000. With an increase in population there is an increase in the demand for healthcare services. In 2002, for every 1,000 residents 71.73 people used ambulatory surgery services at either a freestanding or hospital outpatient facility. Figure 1 charts utilization rates by State Service Delivery Region for 2002. In addition to general population growth, the use-rate of ambulatory surgery services also increases with the age of the population. In a report released by the Center for Disease Control, National Center for Health Statistics, National Ambulatory Medical Care Survey, persons over the age of 45 constituted 53% of physician office visits. Increasing age was positively correlated to the increasing severity of the ailment and complexity of the procedure.

Figure 1. CON REGULATED AMBULATORY SURGERY CENTERS
(Utilization Rates)



Surgical Services in Georgia

There are a number of outpatient surgical facilities available to Georgia residents in both freestanding and hospital-based ambulatory environments. Since 1995, the Department of Community Health has reviewed sixty-six (66) applications for new freestanding ambulatory surgery facilities; 29 of those applicants were approved. In 2002, there were 153 operating rooms dedicated to outpatient surgeries in Georgia's 151 general hospitals. In addition to the dedicated hospital outpatient operating rooms, there were 883 shared operating rooms.

The total number of outpatient surgeries grew by almost 15% between 1998 and 2002, from 507,859 to 598,560 surgeries per year, in both freestanding and hospital-based outpatient settings.

Based on recent information provided by the Department of Human Resources/Office of Regulatory Services has licensed over 201 ambulatory surgery centers. This includes 46 freestanding ambulatory surgery facilities approved through CON review and single-specialty, physician-owned facilities that do not require CON approval. The differences in the number of freestanding facilities between the two Departments (Department of Community Health and Department of Human Resources) are due to

differences in regulatory oversight. The Department of Community Health, by statute, provide no regulatory oversight for those single-specialty, physician-owned facilities that fall below the statutory capital construction threshold. These providers are issued Letters of Non-Reviewabiltity (LNRs) since development of their offices did not trigger the state's capital expenditure threshold.

The Department of Human Resources has the authority to license all ambulatory surgery facilities that seek licensure. Medicare requires that certified ambulatory surgery centers comply with state licensure requirements in order to be eligible for reimbursement through CMS. Ambulatory surgery facilities that wish to participate in the Medicare program must obtain state licensure.

STANDARDS AND RATIONALE FOR RULES
AMBULATORY SURGERY SERVICES
272-2-.09 STANDARDS AND CRITERIA. AMENDED

(l) AMBULATORY SURGERY SERVICES

(a) APPLICABILITY

The law and the rules of the Department of Community Health/Division of Health Planning, require a Certificate of Need (CON) prior to the establishment of new or replacement ambulatory surgery services or for applicants seeking to expand existing surgical services, the cost of which exceeds the CON threshold. This standard was fine-tuned to ensure that applicants are informed of the instances where the rules would specifically not apply and to provide guidance about the Department's regulatory authority.

This rule applies only to those entities required to obtain a Certificate of Need (CON) and shall not apply to those entities otherwise exempt by rule or statute from obtaining a CON, including but not limited to facilities exempt under O.C.G.A.31-6-2(14)(G)(iii). For Certificate of Need purposes, an ambulatory surgery service is considered a new institutional health service if it is to be offered in a free-standing ambulatory surgery facility (ASF).

1. If the ambulatory surgery service is or will be provided as "part of a hospital", the hospital's provision of such service is not subject to CON review under this rule. For purposes of this rule, the following are always considered to be "part of a hospital":
    a. if the service is located within a hospital; or,
    b. if the service is located in a separate building on the hospital's main campus or on separate premises and the service is integrated with other hospital services and systems, and the services are billed through the hospital's Medicare or Medicaid provider number and/or license number issued by the Department of Human Resources.

    The Department of Community Health also will make a determination of reviewability on a case-by-case basis in other situations involving hospitals.

2. The legal entity that develops any ambulatory surgery facility subject to this rule shall be the applicant.

3. A single specialty ambulatory surgery service will be issued a single specialty CON. A new CON will be required for a single specialty ambulatory surgery service to become a multi-specialty service.

4. A party requesting designation as a physician-owned, single-specialty ambulatory surgery service that exceeds the capital expenditure threshold set forth in O.C.G.A. 31-6-2 (14) (G) (iii), and thus is not exempt from CON guidelines pursuant to this statutory provision, will be required to obtain a single specialty CON.

5. These rules do not apply to adult open-heart surgery, adult cardiac catheterization, pediatric cardiac catheterization, pediatric open-heart surgery, and obstetrical services because these services are covered under other CON rules.

6. If an ambulatory surgery facility seeks to expand the number of ambulatory surgery operating rooms and the capital expenditure exceeds the CON threshold, the expansion project will be reviewed under these rules.

7. A replacement ambulatory surgery facility shall not be required to meet the need and adverse impact provisions of this chapter; but shall be required to submit an application and comply with all other provisions of the chapter.

Rationale for Applicability Standard
The Applicability standard sets forth the requirement of a CON for any new, expanded or replacement freestanding ambulatory surgery facility.

Throughout the TAC's deliberation process it became clear that there was a need to clarify when the ambulatory surgical services rules would and would not be triggered. Facilities which operate under the license of or as "part of a hospital" would not be covered by these rules since these services are covered under the service-specific rules that govern short stay general hospital beds. TAC members defined the term "part of a hospital" to make it explicitly clear that the service would have to be offered within the boundaries of the physical plant of a hospital, in a separate building on the hospital's main campus or if the services are billed through the hospital's Medicare or Medicaid provider number and/or license number issued by the Department of Human Resources it would be considered part of a hospital. Additionally, the TAC wanted to continue to provide the Department with some flexibility to make determinations of reviewability on a case-by-case basis for hospital applicants.

Historically, there have been some questions regarding the identification of the applicant authorized to provide ambulatory surgery services. TAC members clarified that the legal entity that developed the ambulatory surgery facility would be applicant. Further, a facility that only offered services in one single-specialty area would be provided with a CON for a single-specialty service (see list of single specialties under definitions section). TAC members clarified that in order for single-specialty ambulatory surgery providers to become multi-specialty providers, a new CON would be required. This process would ensure that there is need for such services and assure that appropriate mechanisms, (e.g. staffing and other quality measures) are in place to support the highest quality of patient care.

At the onset of the TAC's deliberations, Department staff asked TAC members to provide some specific guidance with regard to those applicants requesting Letters of Nonreviewability (LNRs) as single-specialty, physician-owned surgery centers that exceeded the capital expenditure threshold. The TAC determined that the category "Limited Purpose Ambulatory Surgery Center", which in the past designated those facilities that essentially met the criteria for LNR designation with the exception of having exceeded the expenditure threshold, would no longer be used. Instead, any provider exceeding the capital expenditure threshold will be required to obtain a CON as a single-specialty or multi-specialty provider. This is a more streamlined process and provides better specificity around the review process.

The rules clarify that certain surgical procedures including, adult open-heart, adult cardiac catheterization, pediatric cardiac catheterization, pediatric open-heart and obstetrical services are not covered under these rules. This rule further clarifies that these procedures may not be performed in ambulatory surgical facilities. The need, expansion or relocation of these services is governed by other existing service-specific rules.

The Department sought to clarify current regulatory practices which allow health care providers to expand their existing services, providing that the expansion could be accomplished under the CON capital threshold. The Department's current regulatory review practice will continue to allow existing providers

(hospitals and freestanding ambulatory facilities) to increase the number of operating rooms in existing facilities provided that to do so would not trigger the capital expenditure or equipment threshold. Exceeding the capital expenditure threshold immediately triggers CON regulations and would require the submission of a CON.

The TAC wanted to ensure that an existing provider could replace itself should market conditions (i.e. skyrocketing rent) necessitate such a change. This replacement guideline would allow the applicant to replace itself with the same number of operating rooms within a 3-mile radius or less from its current location. TAC members said that a 3-mile radius provides a safeguard to ensure that the applicant would ostensibly continue to serve the same patient base. Applicants seeking to replace their facilities would be exempted from meeting the need and adverse impact statements because they were existing providers in the county but would be required to meet all other standards in the rules. This language is similar to the Short Stay General Hospital rules, which was enacted during the 2003 calendar year.

(b) DEFINITIONS

The rules detail several concepts and policy considerations through the definitions section. The conceptual framework for the definitions is referenced, as appropriate, in the rationale statements throughout this component of the State Health Plan.

1. "Ambulatory surgery" or "ASF" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services (CMS) and the American Medical Association as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed 24 hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

2. "Ambulatory surgery facility" means a public or private facility, not part of a hospital, which provides surgical treatment performed under general or regional anesthesia or monitored anesthesia care (MAC) in an operating room environment to patients not requiring hospitalization. In addition to operating rooms, an ambulatory surgery facility includes all components of pre and post-operative ambulatory surgery care. The term "ambulatory surgery facility" includes, but is not limited to entities such as an "ambulatory surgery center", an "ambulatory surgical treatment center", or by whatever name called meeting the within definition.

3. "Ambulatory surgery operating room" means an operating or procedure room located either in a hospital or in an ambulatory surgery facility that is equipped to perform ambulatory surgical procedures that are invasive and/or manipulative and are identified as surgical procedures in the most recent edition of the Current Procedural Terminology (CPT) coding of the American Medical Association, and is constructed to meet the specifications and standards of the Department of Human Resources. The term operating room also includes endoscopy and cystoscopy rooms and any rooms where scheduled procedures that are billed as surgical procedures are performed.

4. "Ambulatory surgery service" means the provision of ambulatory surgery including pre and post-operative care to patients not requiring hospitalization. An ambulatory surgery service may be provided within hospitals or ambulatory surgery facilities; provided, however, that an ambulatory surgery service provided as "part of a hospital" shall not be subject to these rules.

5. "Ambulatory surgery services patient" means a person who makes a single visit to an operating room during which one or more surgical procedures are performed.

6. "Expansion" or "Expanded Facility" means an existing ambulatory surgery facility that seeks to increase the number of operating and/or procedure rooms and the capital expenditures exceed the CON threshold.

7. "Health planning area" or "planning area" means the twelve (12) state service delivery regions as defined in O.C.G.A. § 50-4-7.

8. "Horizon year" means the last year of a five (5) year projection period for need determinations.

9. "Multi-specialty ambulatory surgery service" means an ambulatory surgery facility offering general surgery or surgery in two or more of the single specialties as defined in Rule 272-2-.09(b)(16).

10. "Not requiring hospitalization" means patients who do not require an inpatient admission to an acute care general hospital prior to receiving ambulatory surgery services, who normally would not require a surgical stay that is overnight or exceeds 24 hours, and who are not expected to require transfer to a hospital for continuing care following the surgical procedure.

11. "Official inventory" means the inventory of all facilities performing or authorized to perform ambulatory surgery services maintained by the Department based on responses to the most recent Annual Hospital Questionnaire (AHQ) Surgical Services Addendum and Freestanding Ambulatory Surgery Services Survey and/or the most recent appropriate surveys, questionnaires and other available official data relating to the provision of ambulatory surgery services, and any ambulatory surgery facilities that have been approved for a CON but are not currently operational or were not operational during the most recent annual survey filing cycle.

12. "Official state component plan" means the same as the "State Health Plan" as defined in Rule 272-1-.01.

13. "Operating room environment" means an environment, which meets the minimum physical plant, health and safety guidelines, and operating standards specified for ambulatory surgical treatment centers in the rules of the Department of Human Resources and the most recent edition of the *Guidelines for Design and Construction of Hospital and Health Care Facilities*, American Institute of Architects Academy of Architecture for Health.

14. "Replacement" means new construction solely for the purpose of substituting another facility for an existing facility with the same or fewer number of operating rooms subject to 272-2-.09(1)(c)(1). New construction may be considered a replacement only if the replacement site is located within a three (3) mile radius or less from the ambulatory surgery facility being replaced. Any new construction of an ambulatory surgery facility not meeting the definition for a replacement shall be required to obtain a CON as a new ASF.

15."Safety net hospital" means the same as "Safety net hospital" as defined in Rule 272-2-.09 (8).

16. "Single specialty ambulatory surgery service" means an ambulatory surgery facility meeting the definition in Rule 272-2-.09(b)(2) and offering surgery in one of the following specialties:

dentistry/oral and maxillofacial surgery,
dermatology,
gastroenterology,
obstetrics/gynecology,
ophthalmology,
orthopedics,
otolaryngology,
neurology,
pain management/anesthesiology,
physical medicine and rehabilitation,
plastic surgery,
podiatry,
pulmonary medicine, or
urology,

as evidenced by board eligibility or certification in the specialty.

17) "Teaching hospital" means the same as "Teaching hospital" as defined in Rule 272-2-.09 (8).

Rationale for Definitions
Several of the definitions that appear above were maintained from the previous edition of the ambulatory surgical services plan. The Department and the TAC felt that, where changes were made, it would be appropriate to discuss how the committee came to its conclusions.

Definition 3 "Ambulatory surgery operating room": Heretofore, surgical procedures that were performed in endoscopy or cystoscopy rooms were not consistently captured in the Department's inventory. The Department and the TAC felt that in order to get an accurate assessment of the need for services and to remove any ambiguity that endoscopy and cystocopy rooms and other rooms where scheduled procedures are performed and billed as surgical procedures, should be accounted for in the need methodology.

Definition 4 "Ambulatory surgery service": Though ambulatory surgery services that were provided as "part of a hospital" were never reviewed under the Department's rules for freestanding ambulatory surgery services, the TAC amended this definition to ensure that there would be no misunderstanding of this practice during the regulatory review process.

Definition 7 "Health planning area": In the past, the Department used "health planning areas" as defined by Rule. However the Short Stay General Hospital TAC, during their development process to update the state health plan, recommended the use of State Service Delivery Regions (SSDRs), as set forth in statute. The ambulatory surgical services TAC concurred with the reasoning of the Short Stay General Hospital TAC.

Definition 8 : "Horizon year" means the last year of a five (5) year projection for need determinations. This language established through rule the written policy of the Department.

Definition 11 "Official inventory": This standard was changed to incorporate those facilities that have been approved but are not yet operational and those that were not operational during the survey cycle. TAC members and Department staff concurred that inclusion of these facilities would provide a more realistic inventory of authorized resources and should be counted when determining the assessment of need.

Definition 13: "Operating room environment" this standard was expanded to incorporate the most recent edition of the *Guidelines for Design and Construction of Hospital and Health Care Facilities,* issued by the American Institute of Architects Academy of Architecture for Health. Members felt that this additional requirement would ensure high quality care and would ensure conformity with current industry standards.

Definition 14 "Replacement": Historically, the Department interpreted the meaning of the word replacement of CON regulated services to mean that construction of a new facility would have been for the sole purpose of substituting another facility for an existing facility with the same number of rooms. Earlier rules governing ambulatory surgical services however did not make an allowance for replacement facilities. TAC members felt that providers should be allowed some flexibility to replace their facilities should market conditions necessitate such a change. Because TAC members expressed concern that this provision could be misused; they inserted language that specified that "replacement" is limited a new facility "with the same number of rooms" and that the replacement facility might be located within a three mile radius of the current facility to ensure continuity of care to the patients.

During the committee's deliberations some members thought that the 3-mile radius was too restrictive while other members felt that the definition was not restrictive enough and should incorporate additional constraints. Following significant committee discussion, members agreed to allow replacement with the same number of rooms within a 3-mile radius or less from the existing ambulatory surgery service. TAC members felt that the 3-miles radius seemed reasonable and justifiable and agreed that an applicant could reasonably contend that they could continue to serve essentially the same patient base within a three-mile radius.

Definition 15 "Safety net hospital": This definition was taken from the Short Stay General Hospital rules that were adopted in 2003. TAC members agreed that the state has an interest in protecting safety net hospitals. These facilities, which include teaching and trauma-designated hospitals, are vital to the state's health care system. Teaching hospitals provide training opportunities for the state's healthcare workforce, provide a disproportionate amount of care to the state's poor and uninsured population and provide highly specialized clinical services. Hospitals designated as trauma facilities require increased resources in order to maintain this designation and to provide the highest quality of care. Children's hospitals and providers of substantial uncompensated and public insurance services also are considered safety net hospitals under this definition.

During the course of the committee discussions, some members asked about the possibility of including "sole community rural hospitals" or "rural referral hospitals" as safety net hospitals. Department staff indicated that the safety net definition should be consistent throughout all of the Department's rules. Further, during the deliberation of the Short Stay General Hospital rule development process, members noted that not every hospital or sole community hospital is a safety net hospital. The list of safety net hospitals is not static and would be updated annually in conjunction with the Georgia Board for Physician Workforce, the Georgia Department of Human Resources and the Department of Community Health.

Definition 16 "Single-specialty ambulatory surgery service": Because there can be significant areas of

overlap in specialty areas and because the Department had requested guidance from the TAC regarding those disciplines that should be considered single-specialty services. TAC members spent a considerable amount of time compiling this list of single-specialty providers. TAC members reviewed materials from other states, medical associations, and societies. Following considerable committee discussion, the TAC delineated those specialties that would be defined as single-specialties. The TAC's position on the list of single-specialty services was generally established by a split vote.

In addition to the single-specialty areas that were apart of the previous edition of the rules, three additional single-specialty areas were added namely, dermatology, neurology and physical medicine and rehabilitation. These single-specialty areas were added given the strength of information from other states, materials from several associations, consideration by the Department, including the issuance of previous Letters of Determination, and extensive committee member input.

Additional recommendations to add other specialties to the list of single-specialty areas were made by TAC members and via correspondence to the TAC. Some additional recommendations included the addition of such disciplines as colon and rectal surgery, general surgery, interventional radiology, and vascular surgery. The Department took the position that general surgery is a multi-specialty discipline. The committee was provided with a copy of the Statement on Scope of Practice and Credentialing issued by the American Society of General Surgeons (ASGS) which states that "general surgery is a comprehensive discipline that encompasses knowledge and experience common to all surgical specialties" and further that general surgeons have "the experience and training to manage common problems in plastic, thoracic, pediatric, gynecologic, urologic, neurologic, and orthopedic surgery". The Department said that this statement from the ASGS confirms the wide breath and scope of practice of the general surgeon and supports the Department's prior rule standard that general surgery is a multi-specialty discipline. The TAC concurred. Because general surgeons have broad latitude to perform a wide range of surgical procedures on all parts of the body, the Department contends that it is a multi-specialty and should remain as such. TAC members endorsed this position by voting overwhelming in support of its exclusion from the list of single-specialties.

The TAC recommended that to ensure greater clarity, the Department should use this list to identify those single-specialty providers that may request a Letter of Nonreviewability (LNR) for designation as a single-specialty, physician-owned, provider. These providers are exempt from CON. Under the TAC's recommendation, the Department would grant LNRs only to those single-specialty providers that appear on this list.

(c) STANDARDS

STANDARD 1: MINIMUM FACILITY SIZE

This standard was established to ensure that applicants are informed of the minimum facility size expectations.

1. A proposed multi-specialty ambulatory surgery service shall have a minimum of three operating rooms. A proposed single-specialty ambulatory surgery service shall have a minimum of two operating rooms.

Rationale for Minimum Facility Size Standard
TAC members felt that it was important to delineate the minimum size expectations for CON regulated ambulatory surgery facilities. Economic realities, including the need to offer sustainable services, coupled with the need to provide high quality care in appropriate settings makes it important to recommend some minimum number of operating rooms. Members agreed that the range of services and the quantity of procedures would justify a higher number of rooms for multi-specialty facilities.

STANDARD 2: NEED METHODOLOGY

The need methodology for ambulatory surgery is essentially the same as that which was used in the 1998 edition of the State Health Plan. However there were several areas that needed to be finetuned and explained to enhance clarity.

2. The numerical need for a new or expanded ambulatory surgery facility shall be determined by a demographic formula which includes the number of ambulatory surgery services cases in a planning area. An ambulatory surgery patient represents one case. The following need calculation applies to each planning area.

(i) determine the current utilization rate for ambulatory surgery services for patients in each planning area by dividing the number of ambulatory surgery services patients served in ambulatory surgery operating rooms, hospital-based and free-standing, as reported in the most recent annual surveys, by the population for the planning area for the survey year;

(ii) determine the projected number of ambulatory surgery services patients in each planning area for the horizon year by multiplying the current utilization rate (step (i)) by the population for the planning area for the horizon year;

(iii) determine the number of operating rooms needed by dividing the number of projected ambulatory surgery services patients (step (ii)) by the optimal utilization per operating room. Capacity per operating room per year is 1,250 patients; optimal utilization is 1,000 patients per operating room per year. (This is based on 250 operating room days per year (50 weeks x 5 days/weeks) x 5 patients per room per day x 80 % utilization.);

(iv) determine the official inventory of ambulatory surgery operating rooms by adding:

(a) The pro-rata portion of hospital shared inpatient/ambulatory surgery operating rooms devoted to ambulatory surgery services. This portion is determined as follows:

$$\frac{\text{(number of ambulatory surgery patients x 90 min.)}}{\text{\{(ambulatory surgery patients x 90 min)+(inpatient surgery patients x 145 min.)\} x number of shared rooms}}$$

(b) Number of hospital dedicated ambulatory surgery operating rooms; and

(c) Number of ambulatory surgery operating rooms in ambulatory surgery facilities; and

(v) determine the projected net surplus or deficit for ambulatory surgery services by subtracting the total ambulatory surgery operating rooms needed (step (iii)) from the official inventory of ambulatory surgery services operating rooms in the planning area.

Rationale for Need Methodology Standard

The need methodology is determined through the application of a numerical need method and an assessment of the aggregate utilization rate of existing services. It has several components including the determination of the number of dedicated ambulatory surgery rooms and the allocation of shared rooms in hospitals. Capacity per operating room per year was determined by the TAC to be 1,250 patients; optimal utilization to be 1,000 patients per operating room per year. An assessment of the other state plans, including Tennessee, Mississippi, Michigan, North Carolina, South Carolina, Rhode Island, West Virginia, State of Washington, show some variation in the average number of patients or procedures per ambulatory surgery operating room per day, with a range from 800-1,377patients or procedures per year. The TAC's recommended number falls between this range. The number of operating rooms meeting the need methodology is based on 1,000 patients per room (250 days/year by 5 patients/day at 80% utilization). The Department moved away from using procedures and moved to using patients in the calculation of the need methodology during the last update of the ambulatory surgery plan and rules. TAC members engaged in a significant amount of discussion in this area and acknowledged that there are advantages and disadvantages to this change. Some TAC members, on one hand, stated that there is a great likelihood that the need could be underestimated if the Department only captured the number of patients; conversely other members stated if the need methodology considered only the number of procedures, there could be an overestimation of the need for services.

In the numerical need, patients are forecasted for the horizon year by using current year rate population data projected forward for five years. Department staff clarified that a 5-year planning horizon has historically been used to forecast the need for acute care services and diagnostic equipment in Georgia. Because there were no major concerns raised about the continued use of the 5-year planning process, members voted unanimously to maintain the 5-year planning horizon.

During the rule development process, TAC members requested and were provided with data from several sources which justified the average time for ambulatory surgery procedures (90 minutes) in this methodology. Supporting materials were provided from Centers for Medicare and Medicaid Services, Federal Ambulatory Surgery Association (FASA) and several states including Kentucky, Montana, North Carolina, and Tennessee.

Among the major differences in these rules when compared with earlier versions is the directive to include operating rooms in freestanding ambulatory surgery centers that have been approved but are not yet operational. This change would allow a more accurate depiction of available resources. A net surplus or deficit of rooms in the numerical need is determined by subtracting the total ambulatory surgery operating rooms needed from the inventory of ambulatory surgery services operating rooms in the planning area. The inventory is determined by using annual survey data. Prior to the approval of a new or expanded ambulatory surgery service, the aggregate utilization of all existing and approved ambulatory surgery services in the planning area should equal or exceed 80% during the most recent year.

Planning area is a critical component of the need methodology. The planning area maps for several other regulated services were recently changed from health planning areas to state's service delivery regions. The Short Stay General Hospital TAC, during their plan update process, recommended the use of SSDRs.

These planning boundaries are used by many agencies for economic and community development planning. In order to ensure uniformity between agencies and common delivery regions, the Short Stay General Hospital TAC recommended that the Department use SSDRs. Ambulatory Surgical Services TAC members requested and were provided copies of the SSDR maps along with an analysis of the impact of such a change. Members voted to adopt this change so that planning can be appropriately aligned with other CON services, which now use State Service Delivery Regions.

STANDARD 3: EXCEPTION TO NEED

In rare instances, the objective need methodology may not detect underlying or subtle problems in service delivery. For this reason, regulatory rules frequently establish mechanisms to seek alternative ways to address these gaps in service delivery. The TAC sanctioned the concept of creating an exception to the need standard for applicants who seek to address atypical barriers to care based on any one or some combination of four value-based criteria: cost, quality, financial access or geographic accessibility.

(a) The Department may allow an exception to the need standards referenced above, in order to remedy an atypical barrier to ambulatory surgery services based on cost, quality, financial access, or geographic accessibility. An applicant seeking such an exception shall have the burden of proving to the Department that the cost, quality, financial access, or geographic accessibility of current services, or some combination thereof, result in a barrier to services that should typically be available to citizens in the area and/or the communities under review. In approving an application through the exception process, the Department shall document the basis or bases for granting the exception and the barrier or barriers that the successful applicant would be expected to remedy.

(b) The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

1. An atypical barrier to services based on cost may include the failure of one or more existing providers of ambulatory surgery services to provide services at reasonable cost, as evidenced by the charges and/or reimbursement for ambulatory surgical services providers in a given planning area being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other similar providers in the state.

2. An atypical barrier to services based on quality may include the failure of one or more existing providers of ambulatory surgery services to provide services with outcomes generally in keeping with accepted clinical guidelines of the American College of Surgeons, peer review programs and comparable state rates for similar populations and/or procedures.

3. An atypical barrier to services based on quality and geographic accessibility also may include consideration that an applicant will provide clinical trials of ambulatory surgical procedures and/or single specialty services not available elsewhere in the planning area that are recognized on the registry of clinical trials maintained by the National Institutes of Health.

4. An atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of one or more existing providers of services within the community to provide services to indigent, charity and Medicaid patients.

5. An atypical barrier to services based on geographic accessibility may include a planning area or county within a planning area which does not have access to ambulatory surgical services, either through a hospital or a freestanding facility, within thirty (30) driving miles.

6. The Department also may consider an exception due to an atypical barrier to services based on geographic accessibility if the applicant is a designated, exempt physician-owned single specialty ambulatory surgery service seeking a CON as a single specialty ambulatory surgery service, and the single specialty service is the only service of its kind in the planning area, including hospital-based or freestanding ambulatory surgery services.

7. An atypical barrier to services based on geographic accessibility also may include consideration that an applicant for a single specialty ambulatory surgery service performs specialty procedures that require considerably more time than the need methodology contemplates (e.g., the complexity of the procedure(s) performed by the board certified specialty limits the number of patients that can be served a day on average) and, as such, the applicant contends that need methodology does not correctly reflect the service demand and need for the specialty. In seeking consideration for such an atypical barrier, an applicant must document to the Department the lack of availability of that discrete specialty within the planning area, either through a hospital or freestanding facility, and must sufficiently document the distinct nature of the services and procedures relative to other procedures measured by the need methodology.

Rationale for Exception to Need Standard:
The Department may allow an exception to the need standard to remedy an atypical barrier to ambulatory surgery services based on cost, quality, financial access, or geographic accessibility. These exceptions to the need provisions can be found in most of the Department's CON rules. The TAC concurred that these exceptions would be appropriate for incorporation into the ambulatory surgery rules. The Department is responsible for managing the state's health planning program, which establishes standards and criteria for awarding Certificates-of-Need to health care facilities and certain specialized diagnostic, or treatment services. The Department uses rigorous need methodologies to help contain health care costs and to avoid the unnecessary duplication of services, equipment and facilities.

Throughout the development of the rules, members noted that there are subtle nuances that are not always appropriately captured by the numerical need methodologies which could impact the need for services. The TAC sanctioned the concept of creating an exception to the need standard for applicants who seek to address atypical barriers to care based on any one or any combination of four value-based criteria: cost, quality, financial access or geographic accessibility. In any submission to seek consideration under the exception provisions, the burden of proof is placed on the applicant to demonstrate that these accessibility problems exist. The rules provide some examples of delivery system problems which might merit consideration as a ground for an exception.

COST: The TAC noted that charges do not equate to reimbursement, particularly in the case of government and third party payors; therefore they felt that it would be important to consider charges as well as reimbursement in any such review. Comparing charges with other services in the same or a similar geographic area also helps ensure equitable charges within individual communities. They agreed that "significantly higher" would be defined as one or more standard deviations from the mean of charges among similar types of providers.

QUALITY: The TAC spent a significant amount of time discussing the issue of quality of care and its importance in the provision of ambulatory surgical services. The rules reflect that an atypical barrier based on quality may include the failure of existing providers to provide services with outcomes generally in keeping with accepted clinical rules of the American College of Surgeons, peer review programs and comparable state rates for similar populations. Further, that an exception to the need could be granted for an applicant who will be participating in clinical trials, recognized on the registry of clinical trials maintained by the National Institutes of Health (NIH). The NIH clinical trials are well established and incorporate stringent quality standards, including followup protocols.

FINANCIAL ACCESS: One of the core goals of the Department is to develop and sustain a health care infrastructure that is responsive to consumers while improving access and coverage. This includes planning for coverage of uninsured and underinsured Georgians, currently estimated at 1.3 million people. As the state Medicaid agency, the Department also must ensure that citizens using this health care plan receive equitable access to coverage. The TAC felt strongly that providers should assume some of the responsibility for providing care to its local residents, particularly those that may have limited financial resources.

The Department is committed to ensuring that providers take responsibility for the health care of their local areas by serving as a conduit for the provision of local health care services regardless of the patients' ability to pay. For these reasons, the rules acknowledge that an atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of existing providers within the community to provide services to indigent, charity and Medicaid patients. The comparison should be done among providers within the applicable state service delivery region.

GEOGRAPHIC ACCESS: Ambulatory surgical services should be accessible to all residents in the State of Georgia. The TAC concurred that the Department could allow an exception to the need methodology if the applicant is a designated single-specialty, physician-owned ambulatory surgery service seeking a CON as a single-specialty ambulatory surgery service and the single specialty service is the only one of its kind in the planning area. This would allow residents in local communities access to appropriate services. Members felt that it would be prudent to allow an existing provider, with an established relationship in the community the opportunity to expand existing services to address community need. Additionally, TAC members felt that those providers that perform procedures that require significantly larger amounts of time and are more highly complex in nature, as signified by the providers' inability to see a large number of patients per day, should be given some special consideration. Members agreed that the numeric need methodology, in this instance, might not adequately reflect the need for such specialized services due to the additional time demands of such procedures which fall outside of the average time for ambulatory surgery procedures as is defined in the current need methodology, and which could not be adequately accounted for in the need methodology. Applicants would be required to document the lack of availability of such specialized services within the planning area, including hospital-based services or other freestanding facilities.

STANDARD 4: ADVERSE IMPACT

Adverse impact rules protect the human and financial investment that has been made by the state and existing providers. Starting a new program to the detriment of existing programs, particularly the state's safety net providers is not in line with sound planning principles. The TAC agreed that safety net providers should be afforded some protection given indigent and charity care missions. Members agreed that

ambulatory surgical services should be developed in an orderly and comprehensive manner with a goal of minimizing adverse impact on the existing delivery system.

(a) Prior to approval of a new or expanded ambulatory surgery facility in any planning area, the aggregate utilization rate of all existing and approved ambulatory surgery services in that planning area shall equal or exceed 80 percent during the most recent survey year; and

(b) An applicant for a new or expanded ambulatory surgery facility shall demonstrate in its application that the addition of the service will not be detrimental to safety net hospitals within the planning area. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in ambulatory surgery services market share and payer mix for the applicant and any safety net hospitals. A total decrease in ambulatory surgery procedures of 10% or more for any safety net hospital shall be considered detrimental.

Rationale for Adverse Impact Standard

An applicant seeking to provide ambulatory surgical services would be required to meet the need methodology and, in addition, the aggregate utilization rate in the applicant's planning area must equal or exceed 80% during the most recent survey year before additional services can be initiated. This would ensure that all existing resources are being efficiently utilized. In addition to these standards, an applicant would be required to address impact on any safety net hospitals in the planning area.

TAC members agreed that safety net providers within the state service delivery region of an applicant should be afforded some stipulated protection. Safety net providers are defined as hospitals meeting at least two key criteria – uncompensated charges for indigent and charity care patients constitute 10% or more of hospital adjusted gross revenue, uncompensated charges for indigent patients constitute 6% or more of hospital adjusted gross revenues, Medicaid and PeachCare inpatient admissions constitute 20% or more of the total hospital inpatient admissions, trauma center designation, and teaching or children's hospitals.

The TAC agreed that the state has an interest in ensuring the stability of safety net hospitals because they, among other things, operate in high-risk environments, provide expensive services, provide valuable teaching opportunities for the state's healthcare workforce, and provide a significant amount of the state's uncompensated healthcare services.

In order to determine whether a safety net provider has been negatively impacted, an applicant should present analyses detailing projected changes in market share and payor mix for the applicant and any safety net hospitals. Impact on an existing safety net hospital shall be determined to be adverse if, based on the projected utilization, any existing safety net hospital within the planning area would have a total decrease of 10% or more in the number of ambulatory surgery procedures.

STANDARD 5: FINANCIAL ACCESSIBILITY

TAC members agreed that financial access to care is a key component of the state's planning process. Further, they agreed that the equitable distribution of the indigent care burden among providers is the corollary to the equitable access to hospital and health care services for all citizens without regard to the ability to pay. Assessment of an ambulatory surgical service's commitment to assure financial access to services should be multifaceted.

An applicant for an ambulatory surgery facility shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

(i) providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay;

(ii) providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the ambulatory surgery service;

(iii) providing a written commitment to participate in the Medicare, Medicaid and PeachCare programs;

(iv) providing a written commitment to participate in any other state health benefits insurance programs for which the ambulatory surgery service is eligible; and

(v) providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, PeachCare, and indigent and charity patients.

Rationale for Financial Accessibility Standard

The Department is fully committed to the standard of financial access and the provision of care to the state's indigent, low-income and uninsured population. This standard is a part of all of the Department's current rules. Providers in the State of Georgia are expected to adhere to these standards as critical criteria for receiving any business or operational approval from the state. Providing full access, free from financial or any other discrimination, is central to Georgia's health care purchasing and regulatory mission. These provisions are a part of a standard template that all CON applicants must address to demonstrate how they plan to meet the expectation of providing care to the state's indigent and low-income and uninsured patients.

The TAC endorsed the Department's mission and agreed that all applicants should minimize barriers to appropriate health care services. TAC members unanimously recommended the inclusion of this accessibility standard.

Applicants for new, replacement or expanded services would be required to provide evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis, including providing services to individuals regardless of race, sex, ability to pay. The TAC recommended that applicants should provide written commitment that services for indigent and charity care patients will be offered at a standard which meets or exceeds three percent (3%) of annual adjusted gross revenues for the ambulatory surgery service. The TAC agreed that this standard is critical to ensuring access to care for patients who might not otherwise have access to such services. Applicants also must provide full access to services, regardless of ability to pay or payment source, and are required to agree to participate in any state sponsored or operated health insurance program. In evaluating the past record of performance of the applicant, the Department should consider the record of the applicant and any affiliates. Failure to meet an existing or previous indigent care commitment and/or failure to serve the Medicaid or indigent population at

or above a level commensurate with the community served by the applicant and/or its affiliates may be grounds for denial of an application. The Department will use data from the three most recent prior years to make this determination.

The state's current standard commitment requires CON applicants to commit to provide indigent/charity care in an amount that is equal to or greater than 3%. At the present time, only one regulated service (Positron Emission Tomography) is required to provide a commitment higher than 3%. Members of the PET TAC agreed that increasing the indigent/charity care commitment would be a mechanism to increase access to these diagnostic services since Medicaid currently does not reimburse those services. Following significant discussion, TAC members agreed that a commitment of 3% would be appropriate and would be required for all applicants seeking to offer freestanding ambulatory surgical services.

STANDARD 6: FAVORABLE CONSIDERATION

TAC members agreed that there might be circumstances where competing applications may have comparable characteristics. When competing applications are all worthy of merit and only one applicant can be given approval, the applicant that has historically provided increased access to care should be given favorable consideration.

In considering applications joined for review, the Department may give favorable consideration to whichever of the applicants historically has provided the higher annual percentage of unreimbursed care to indigent and charity patients and the higher annual percentage of services to Medicare, Medicaid and Peach Care patients.

Rationale for Favorable Consideration Standard:

The favorable consideration standard is triggered only in instances where there are competing applications. In the case of competing but otherwise generally comparable applications, an applicant that has historically provided the higher annual percentage of unreimbursed care to indigent and charity care patients and the higher annual percentage of services to Medicare, Medicaid and PeachCare patients should be awarded the Department's approval. This is an issue of accessibility to appropriate services. The TAC has endorsed the Department's mission of improving health status and health outcomes for all Georgians by continuing to require providers to minimize barriers to the accessibility of health care services. The Department may give special consideration, when considering competing applications, to the applicant that has a stronger record of serving these eligible patient populations.

STANDARD 7: QUALITY OF CARE

TAC members said that providing the highest quality care to the residents of the state is among the state's and the TAC's highest priorities. In an effort to promote improved health outcomes for families, all providers should be expected to maintain some minimal quality standards.

(a) An applicant shall provide evidence of a credentialing process, which provides that surgical procedures will be performed only by licensed physicians or by licensed oral and maxillofacial surgeons or by licensed podiatrists who are board certified/qualified by one of the boards, recognized by a specialty board recognized by the American Board of Medical Specialties (ABMS) or by the American Osteopathic Association (AOA), or by the American Board of Oral and Maxillofacial Surgery (ABOMS) or by the Council on Podiatric Medical Education and are board certified/qualified by such other board which is nationally

recognized and has been deemed acceptable to and qualified as an equivalent such board as determined and certified at the sole discretion of the applicant's state licensing board. The applicant shall stipulate that the surgical procedures to be performed will be limited to those that are generally recognized as falling within the scope of training and practice of the surgeons providing the care.

(b) An applicant shall assure that the physicians or oral and maxillofacial surgeons performing surgical procedures will maintain privileges at an accredited or state licensed hospital in their geographic area for the procedures they perform in ambulatory surgery settings.

(c) An applicant shall assure that anesthesia will only be administered by an anesthesiologist, by a physician qualified to administer anesthesia, by an oral and maxillofacial surgeon, or by a certified registered nurse anesthetist; and that the anesthesia levels, patient selection and screening criteria, and pre-operative and post-operative guidelines of the American Society for Anesthesiologists (ASA) guidelines, or the guidelines of the American Association of Oral and Maxillofacial Surgeons (AAOMS) or the *Scope and Standards for Nurse Anesthesia Practice* issued by the American Association of Nurse Anesthetists (AANA) and will be followed and so documented.

(d). An applicant shall assure that at least one physician, oral and maxillofacial surgeon or CRNA who is currently certified in advanced resuscitative techniques equivalent to Advanced Cardiac Life Support (ACLS), Advanced Trauma Life Support (ATLS) or Pediatric Advanced Cardiac Life Support (PALS), as appropriate, must be on the premises until all surgical patients have been determined to be medically stable and such determination has been properly entered in each patients' anesthesia or recovery room record by the physician, oral and maxillofacial surgeon or CRNA in charge of administering the anesthesia. Thereafter, a licensed Registered Nurse who is currently certified in ACLS, ATLS or PALS must be on the premises until all patients are medically discharged by the facility. In addition, the applicant shall assure that other medical personnel with direct patient contact will, at a minimum, be certified in Basic Cardiac Life Support (BCLS).

(e) An applicant shall submit evidence that qualified personnel will be available to insure a quality service to meet licensure, certification and/or accreditation requirements.

(f) An applicant shall submit a policy and plan for reviewing outcomes of patient care and a plan for ongoing quality improvement activities, including a stated set of criteria for identifying those patients to be reviewed and a mechanism for evaluating the patient review process.

(g) An applicant shall submit written policies and procedures for utilization review consistent with state, federal, and accreditation standards. This review shall include review of the medical necessity for the service, appropriateness of the ambulatory surgical setting, quality of patient care, and rates of utilization.

(h) An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Georgia Department of Human Resources.

(i) An applicant that has previously operated and/or owned any type of health facilities in Georgia also shall provide sufficient documentation that any facilities currently or previously in business have no history of licensure adverse actions and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three (3) years and have no current outstanding licensure and Medicare and/or Medicaid certification deficiencies.

(j) An applicant for a new or replacement ambulatory surgery service shall provide a statement of intent to meet, within 12 months of obtaining state licensure, the appropriate accreditation requirements of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAASF) and/or other appropriate accrediting agency.

(k) An applicant for an expanded ambulatory surgery service shall provide documentation that they fully meet the appropriate accreditation requirements of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (ASF) and/or other appropriate accrediting agency.

Rationale for Quality of Care Standard

The State of Georgia and the TAC have an interest in ensuring that all ambulatory surgical facilities provide the highest quality of care to patients. This plan incorporates requirements that ensure, among other things, a credentialing process, appropriately trained personnel and patient care review process. Given this commitment, the ambulatory surgical services quality standards encapsulate the standards, guidelines and rules of the American Society of Anesthesiologists, American College of Surgeons ACS), American Association of Nurse Anesthetists (AANA), and American Association for Accreditation of Ambulatory Surgery Facilities (AAASF), American Association of Oral and Maxillofacial Surgeons (AAOMS), and Council on Podiatric Medical Education (COPME), among others.

It is a recognized and accepted medical standard that physicians providing ambulatory surgery services perform only those procedures that are defined within the scope of their license and in accordance with individually granted clinical privileges. Limiting the privileges of a surgeon within an ambulatory surgery center to only those for which he/she is granted by an accredited hospital helps to ensure high quality patient care services.

The administration of anesthesia carries significant risk. To ensure quality of care and patient safety, qualified personnel who have specialized knowledge, skill and training in the administration of anesthesia should be the only persons authorized to perform this procedure and these qualified clinicians should be on hand at all times a surgical patient is present in the event of an emergency. The TAC engaged in discussions about the types of clinical personnel who are authorized to perform anesthesia services in the state. Members agreed that all clinical personnel that are authorized to provide anesthesia services should adhere to the respective practice rules of their national accrediting body. In this case, anesthesiologists or physician qualified to administer anesthesia; should adhere to the practice rules of the American Society of Anesthesiologists, oral Maxillofacial Surgeons should adhere to the practice rules of the American Association of Oral and Maxillofacial Surgeons (AAOMS), and Certified Registered Nurse Anesthetists should adhere to the practice rules of the American Association of Nurse Anesthetists. Laws of the State of Georgia require that anesthesia may be administered by CRNA, provided that it is administered under the direction and responsibility of a licensed physician, or a duly permitted oral and maxillofacial surgeon and in compliance with all applicable statues, rules and regulations. Members recommended that this specific language be added to the rules to ensure high quality patient care for Georgia citizens and to ensure conformity with state law. Further, members wanted to ensure that no perception of an expansion of scope of services for CRNAs. Additionally, the applicant is required to have appropriate personnel on site that

are qualified to perform advanced resuscitative techniques and other appropriate care until all patients are medically discharged.

An ambulatory surgery service should demonstrate that qualified personnel would be available to insure a quality service to meet licensure, certification and/or accreditation requirements. Additionally, ambulatory surgery facilities should have a policy and plan for reviewing patient care, including criteria for identifying those patients to be reviewed and a mechanism for evaluating the patient review process. TAC members also agreed that ambulatory surgical service providers should ensure that policies that incorporate procedures for patient care management and quality assurance are in place. Members agreed that incorporating written policies and procedures for utilization review helps to ensure quality of care, patient safety, and appropriate application and utilization of ambulatory surgery services. The Department is fully committed to ensuring that providers offer the highest possible quality of patient care. The Department and the TAC want applicants to plan for services in a comprehensive manner recognizing staff limitations and keeping the best interest of patients at the forefront of the process.

Compliance with licensure and certification standards, both national and state, correlates to the successful operation and management of ambulatory surgical facilities and indicates that a facility has met certain performance standards. The Joint Commission on Accreditation of Health Care Organization (JCAHO) is the nation's major accrediting body. Accreditation by this or another nationally recognized accrediting body is usually acknowledged as a quality "seal of approval". Because these standards reflect state-of-the-art performance expectations, organizations that meet them improve their ability to provide quality patient care. JCAHO performs on-site visits and establish standards that address all aspects of care in ambulatory surgical facilities including, but not limited to, governance and administration, quality assurance and medical records. Accreditation may also be a condition of reimbursement for certain insurers and other payors. JCAHO accreditation provides deemed status for Medicare regulations. The state's current rules require accreditation by Joint Commission for Accreditation of Healthcare Organizations, (JCAHO), Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities, Inc., (ASF) or other appropriate agencies.

Hospital affiliation and transfer agreements, credentialing processes and letters of intent to comply with all appropriate licensure regulations are among Georgia's required quality rules. The applicant would be required to provide sufficient documentation to prove its intent to comply with all appropriate licensure requirements and operational procedures required by the Georgia Department of Human Resources. The Department is committed to working with the Department of Human Resources/Office of Regulatory Services to ensure that applicants have a history of compliance with licensure and other operating standards. An applicant that has previously operated an/or owned any type of health facilities in Georgia also shall provide sufficient documentation that any facilities currently or previously in business have no history of licensure adverse actions and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three (3) years and have no current outstanding licensure and Medicare and/or Medicaid certification deficiencies.

Members further agreed that quality assurance standards should be included in the rules of freestanding ambulatory surgery facilities. Nationally, the rise in medical errors causes much concern to patients, providers and payors. Requiring that providers participate in a statewide or national external reporting and utilization review system will help to ensure patient safety and medical errors receive appropriate attention. Further, the facility could benefit from any outcome data that could be used to compare itself to industry benchmarks, which would address such areas as patient outcomes, consumer satisfaction, and consumer

demand.

STANDARD 8: CONTINUITY OF CARE, VIABILITY AND COST CONTAINMENT

Services offered in freestanding ambulatory surgical settings are only one point of access in the healthcare continuum. Members agreed that these services should be coordinated and should be developed to assure patient access and resource sustainability in local communities.

(a) Each applicant shall have a hospital affiliation agreement and/or the medical director must have admitting privileges and other acceptable documented arrangements to insure the necessary backup for medical complications. The applicant must provide written evidence of a binding transfer agreement that documents the capability to transfer a patient immediately to a hospital with adequate emergency room services.

(b) An applicant shall submit written policies and procedures regarding discharge planning. These policies should include, where appropriate, designation of responsible personnel, participation by the patient, family, guardian or significant other, documentation of any follow-up services provided and evaluation of their effectiveness.

(c) An applicant shall demonstrate that the proposed services will be coordinated with the local existing health care system.

(d) An applicant shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the facility.

(e) An applicant shall demonstrate that proposed charges and/or reimbursement rates for services shall compare favorably with charges and/or reimbursement rates for other similar services in the planning area when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for ambulatory surgery services, the Department may compare the applicant's history of charges and/or reimbursement rates, if applicable, with other services in the planning area(s) previously served by the applicant or its parent company.

Rationale for Continuity of Care, Viability and Cost Containment Standard

The ability to transfer ambulatory surgery patients to hospitals in both emergency and non-emergency situations is critical to ensuring optimum patient safety and care. This standard is in keeping with licensure, JCAHO and other appropriate accrediting agency standards. A documented plan for patient transfer helps ensure that necessary services are coordinated and in place when needed.

The Department and the TAC believe that it is important that discharge plans be carefully communicated and coordinated with appropriate healthcare facilities/agencies/providers in the community to ensure an efficient and effective delivery system. Community linkages and coordination could include agreements with other related community service providers. TAC members wanted to encourage providers to work together to provide the highest quality care for their local communities. Members said that increased communication at the local level could result in enhanced quality patient care and increased accessibility of care to patients and their families, decreased healthcare cost and improved system efficiencies.

Providers are encouraged to establish working agreements with community service agencies to enhance and to assure continuity of care through the streamlining of patient referrals and the development of cross-continuum care plans.

Average charges for ambulatory surgery procedures can vary significantly from one geographic area to another. Comparing the reasonableness of charges and or reimbursement rates for other similar services in the planning area helps to ensure reasonable access to services within individual communities. The Department also will compare the applicant's history of charges/reimbursement rates previously served by the applicant or its parent company. This historical perspective provides the Department with some baseline behavior expectations regarding the applicant's likeliness to comply with current commitments.
TAC members agreed that applicants seeking new, expanded or replacement facilities should be required to provide evidence of availability of resources for the provision of services. The rules require applicants to provide evidence that they can fully support, with human resources and capital, this undertaking. Through this requirement, the Department and the TAC want to ensure that health planning is done in a comprehensive manner and in the best interest of the patient.

STANDARD 9: DATA AND INFORMATION REPORTING REQUIREMENTS

In order to project service needs, address quality, and efficiency of ambulatory surgery services it is of critical importance to be able to collect and analyze system-wide data.

An applicant for an ambulatory surgery facility shall document an agreement to provide all Department requested information and statistical data related to the operation and provision of ambulatory surgery and to report that data to the Department in the time frame and format requested by the Department. This information may include, but not be limited to, financial data, patient and procedure volume, utilization and charge data, and any changes in number of ambulatory surgery operating and procedure rooms that may occur as a result of service expansion.

Rationale for Data and Information Reporting Requirement Standard :
The TAC unanimously recommended the inclusion of data and information requirements. The need methodology will require provider data for certain components and uniform data is essential to assess changing patterns and to project service needs relevant to the provision of services. The Department administers an annual survey to collect uniform data from providers. The survey requests both financial data and information regarding such items as patient origin, number of operating rooms, etc.

As additional emphasis is placed on quality, patient outcomes, cost and other efficiency indicators, collection of data will allow more precise assessment of these factors as well as others which are important to health planning. Uniform data would allow more precise assessment of the level of service availability and utilization. Applicants will be required to provide data related to the operation and provision of services to the Department by the requested time.

GOALS, OBJECTIVES AND RECOMMENDED ACTIONS

A. GOAL

Ensure that Georgia citizens have access to cost-effective, efficient and high quality ambulatory surgery services.

B. OBJECTIVES

- Improve access to ambulatory surgery services by authorizing these services based on an objective numerical need methodology;.
- Minimize adverse impact on the state's safety net hospitals;
- Ensure financial access to care by requiring the provision of services to indigent and low-income patients and by ensuring provider participation in Medicaid, PeachCare and other public reimbursement programs;
- Foster an environment which assures access to services for individuals unable to pay and regardless of payment source or circumstance and on a non-discriminatory basis;
- Encourage continuity of care for ambulatory surgery patients within their local communities.
- Ensure quality and patient safety through compliance with appropriate accreditation standards and licensure rules;
- Analyze the availability, quality and effectiveness of services being provided through collection and analysis of information and statistical data.

C. RECOMMENDED ACTIONS

The Ambulatory Surgical Services Technical Advisory Committee discussed and recommended the following actions:

- Implement Certificate of Need (CON) rules for ambulatory surgery services consistent with this Component Plan and approve CON applications accordingly.
- Require providers to demonstrate plans whereby their services are effectively and efficiently coordinated with other existing healthcare services within the community;
- Require providers to demonstrate the intent to achieve optimal clinical, licensure and accreditation standards recently established by JCAHO, AAAHC, ASF, or other appropriate accrediting agencies;

- Require providers to demonstrate administrative policies showing they provide services on a non-discriminatory basis;

- Require providers to demonstrate appropriate hospital affiliation agreements and transfer capabilities;

- Collect data annually, and on an ad hoc basis as needed, to maintain current, accurate information related to availability, quality and effectiveness of services being provided and;

D. OTHER IDENTIFIED ISSUES OUTSIDE OF THE TAC'S PURVIEW

During the Ambulatory Surgical Services TAC plan and rules development process several opportunities were provided for public comment and input. The TAC received correspondence that outlined several policy recommendations. Many of these policy recommendations referred specifically to single-specialty, physician-owned ambulatory surgery centers that are exempt from CON regulation pursuant to O.C.G.A. 31-6-2(14)(G)(iii). The Ambulatory Surgical Services TAC recognized that these recommendations were outside of the purview of their work and neither addressed nor deliberated these policy recommendations, some of which were conflicting. Some TAC members suggested that consideration be given to requiring CON exempt facilities to commit to data reporting requirements and indigent and charity care commitments.

REFERENCES

Federated Ambulatory Surgery Association, National Office Staff, wwww.FASA.org

Georgia Department of Community Health, Department of Health Planning, 1998 Freestanding Ambulatory Surgical Services Component Plan. June 1998

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